



## UNITED STATES DEPARTMENT OF COMMERCE

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I.D.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/185,904	11/03/98	ANDERSON	C 660088,420

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000500 HM22/0118  
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 6300  
SEATTLE WA 98104-7092

EXAMINER

RUBINSON, P

ART UNIT PAPER NUMBER

1653

45

DATE MAILED:

01/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/185,904	ANDERSON ET AL.
	Examiner Patricia A. Robinson	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 October 2000.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 1-41 and 58-101 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 42-57 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

- |  |  |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Drawings***

Applicants were required to submit a proposed drawing correction in reply to the Office action dated 4/25/2000. However, Applicants have chosen to defer formal correction of the noted defect until the application is allowed by the examiner.

### ***Response to Amendment***

The amendments filed in Paper No. 13 filed 10/30/2000 was received, entered and considered. The CRF required for the application was received and entered.

Claims 1-101 are pending, Claims 1-41 and 58-101 are withdrawn from consideration as being directed to a non-elected invention, Claims 42-57 will be examined on the merits.

### ***Response to Arguments***

Applicant's arguments filed on 10/30/2000 have been fully considered but they are not persuasive.

The rejection of claims 42-57 under 35 U.S.C. § 112, 1<sup>st</sup> is maintained.

The rejection of claims 42-46 under 35 U.S.C. § 102(a) is maintained.

The rejection of claims 43-57 under 35 U.S.C. § 103(a) is maintained.

The rejection of claims 43-50 and 52-55 under 35 U.S.C. § 103(a) is maintained.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the description of the claimed invention in the specification is sufficient to reasonably convey to a person having ordinary skill in the art that the applicants, at the time of filing, had possession of the claimed invention. Applicants concede that the prior art and the instant application teach over 30 adenine nucleotide translocator (ANT) polypeptides from a variety of organisms, that several organisms encode two or three isoforms, and that the structure of the family is highly conserved. (See Response, page 3, 1<sup>st</sup> paragraph). Applicants also concede that there are a number of functional properties associated with ANT polypeptides, and that there are a number of structural and functional properties shared among the species within the claimed genus. (Id.)

The fact that the instant specification does not disclose which of these attributes are represented by their small and limited number of disclosed species, applicant has failed to adequately describe the genus claimed in claims 42-57.

In addition, applicants claim 'fragments' and 'variants' of ANT polypeptides but give no direction, guidance or examples as to parameters under which such additional

ANT polypeptides may be obtained. Again, applicants have failed to provide an adequate written description as to what the common core/bond is that these ‘fragments’ and ‘variants’ species must retain in order to remain within the ANT genus by exhibiting ‘essentially’ the same biological function or activity.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 42-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Marzo et al.

Applicants argue that the Marzo et al. reference fails to teach every limitation of the claimed invention. In particular, Marzo et al. fails to teach “isolated ANT produced recombinantly or purified human ANT” and the Marzo reference only teaches “the purification of endogenous and naturally expressed ANT from rat myocardium.” (See Response, page 4, last paragraph).

The fact that applicant arrives at the same product via a different process does not negate the fact that the product is anticipated, unless applicant can demonstrate that one, the process utilized is novel, or two, the product generated by the product is patentably distinct from the product disclosed in the prior art. Applicants have done neither, therefore the mere fact that the product is derived via an alternative process is not persuasive in regard to the Marzo et al. and the Fiore et al. references.

In addition, applicants argue the Fiore et al. fails to teach an isolated human ANT polypeptide, but concedes that Fiore et al. does teach the ANT polypeptide sequence, including the one for human ANT. (See Response, page 5, last paragraph). Again, the fact that Fiore et al. did not isolate the human ANT polypeptide does not obviate the fact that the human ANT polypeptide sequence was disclosed in the prior art before applicants' instant application.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 43-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore et al. in further view of Rosenberg.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Fiore reference teaches one method for purifying ANT using a histidine tag for immobilizing the polypeptide during metal affinity chromatography. (See page 144, Col. 1, last paragraph), however, the Rosenberg reference, as applicants state, is a general

reference that teaches additional methods of purifying polypeptides utilizing fusion protein techniques which incorporate the use of affinity tags including histidine. (See Response, page 7, first paragraph). Thus, the Rosenberg reference is not merely cumulative, for it would have been obvious to one of ordinary skill in the art to try and identify alternative and improved methods of purification of a polypeptide that was currently difficult to purify and/or monitor, as applicants have stated was the case with the ANT polypeptide. (See Response, page 7, second paragraph; and page 8, last paragraph).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 43-50 and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adrian et al. in view of Fiore et al.

Applicants argue that although the Adrian et al. reference teaches the expression of fusion proteins consisting of *Saccharomyces cerevisiae* ADP/ATP translocator (ANT) proteins fused to the enzyme  $\beta$ -galactosidase to identify which amino acids are important in targeting the protein to the mitochondrial membrane, but does not teach the use of

human or animal ANT fusion proteins and the Fiore reference teaches the amino acid sequence of ANT polypeptides from humans and other animals, that there is no suggestion in either reference to derive the ANT polypeptides or fusion proteins of the instant case. (See Response, page 8, last paragraph and page 9, first paragraph). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one of ordinary skill in the art to substitute human or animal ANT instead of the disclosed yeast ANT in order to study the mitochondrial localization sequences in human and animal ANT.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

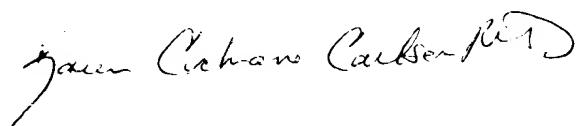
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Robinson whose telephone number is 703-305-0096. The examiner can normally be reached on 8:00 - 4:30 Monday - Friday, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

PAR  
January 15, 2001



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER